ELSEVIER

European Journal of Cardio-thoracic Surgery 31 (2007) 22—25

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

www.elsevier.com/locate/ejcts

Endoscopic off-pump aortic valve replacement: does the pericardial cuff improve the sutureless closure of left ventricular access?☆

Piergiorgio Tozzi [a,*], Malgorzata Pawelec-Wojtalic [b], Dorota Bukowska [c], Vassilios Argitis [a], Ludwig K. von Segesser [a]

[a] *Cardiovascular Surgery Department, University of Lausanne CHUV, Rue du Bugnon 46, 1011 Lausanne, Switzerland*
[b] *Department of Pediatric Radiology, University of Medical Science, Poznań, Poland*
[c] *Department of Veterinary Medicine, University of Agricolture, Poznań, Poland*

Received 3 April 2006; received in revised form 25 June 2006; accepted 4 July 2006; Available online 6 September 2006

Abstract

Objective: Off-pump trans left ventricular approach provides more precise deployment of stented aortic valve of any size with respect to the endovascular replacement. One of the key steps of this procedure is the ventricle repair after catheter withdrawing. We designed an animal study to compare the consistency of a sutureless repair of the left ventricle access using nitinol occluder with and without pericardial cuff on the ventricular side. **Methods:** Material description: The Amplatz-nitinol occluder consists of two square heads squeezing ventricle wall in between them, sealing the defect. To improve its sealing property, a pericardial patch was sutured to the ventricular head of the occluder. Animal study setup: In adult pigs, a 30F sheath was inserted into the epigastric area through the cardiac apex, up to the left ventricle, simulating the approach for off-pump aortic valve replacement. The sheath was then removed and the ventricle closed with standard occluder in half of the animals, and cuffed occluder in the other half. Animals were followed-up for 3 h, collecting haemodynamics data and pericardial bleeding. **Results:** Device was successfully deployed in 12 animals in less than 1 min. In the group where the standard occluder was used, bleeding during the deployment was 80 ± 20 ml and after the deployment was 800 ± 20 ml over 3 h. In the group where the cuffed occluder was used, bleeding during the deployment was 85 ± 20 ml and after the deployment was 100 ± 5 ml over 3 h. In the cuffed group, bleeding was significantly lower than the standard group, p-value being <0.001. **Conclusions:** The occluder is easy to use and the pericardial cuff dramatically increases its efficacy as demonstrated by a significant reduction of blood loss. The cuffed occluder opens the way for endoscopic, off-pump, transventricular aortic valve replacement.

Keywords: Aortic valve replacement; Stented aortic valve; Suturless closure cardiac defects

1. Introduction

In May1965, Davies et al. [1] first published the results of 12 patients suffering from aortic insufficiency, in which they replaced the aortic valve without the assistance of the extracorporeal circulation. They deployed a catheter-mounted homograft aortic valve above the aortic valve using an endovascular approach, and even if they demonstrated the feasibility of the procedure, results were far from the on-pump technique. Since then, many other authors have modified and improved the endovascular approach for aortic valve replacement (AVR) using stented biologic valves [2—4]; however, after 40 years, the endovascular approach for AVR still presents several limitations that can be summarised as follows: (1) the size of the valve is limited by the delivery sheath diameter, therefore, only small stented valves can be implanted; (2) the precise positioning of the stented valve onto the aortic annulus or in supra-annular position is cumbersome because it is very difficult to properly drive long and stiff catheters into the arterial tree. One potential solution is the off-pump trans left ventricle approach (Fig. 1). If the delivery sheath is inserted directly into the cardiac apex, the so called transventricular approach, it would be easier to handle the deployment process without any limitation of the valve size. This concept has already been demonstrated in our previous animal studies [5,6]. However, the limiting factor of this procedure is the ventricle repair after catheter withdrawing. The closure of the left ventricle access is a challenging procedure even when the open chest approach supported with extracorporeal circulation is used. Moreover, there is a consistent risk of systemic air embolism with catastrophic clinical consequences.

Recent developments of sutureless devices for endovascular repair of interatrial septal defects could give us the right tool to easily and safely close the ventricle access. Those devices, however, have not been developed to deal with

☆ Presented at the joint 19th Annual Meeting of the European Association for Cardio-thoracic Surgery and the 13th Annual Meeting of the European Society of Thoracic Surgeons, Barcelona, Spain, September 25—28, 2005.

* Corresponding author. Tel.: +41 21 314 23 08; fax: +41 21 314 22 78.
E-mail address: Piergiorgio.Tozzi@hospvd.ch (P. Tozzi).

1010-7940/$ — see front matter
doi:10.1016/j.ejcts.2006.07.027

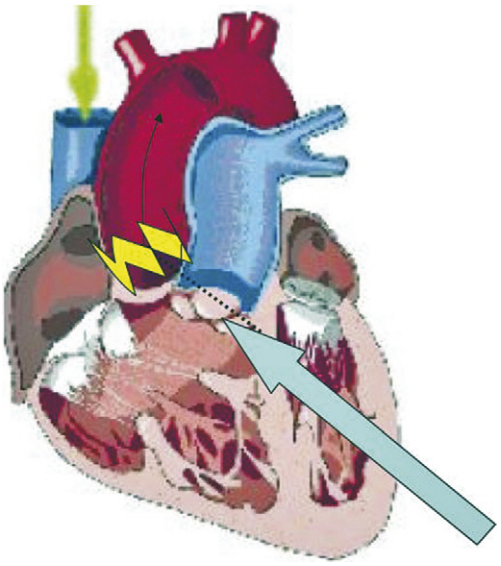

Fig. 1. Schematic representation of the off-pump AVR with the left transventricular approach.

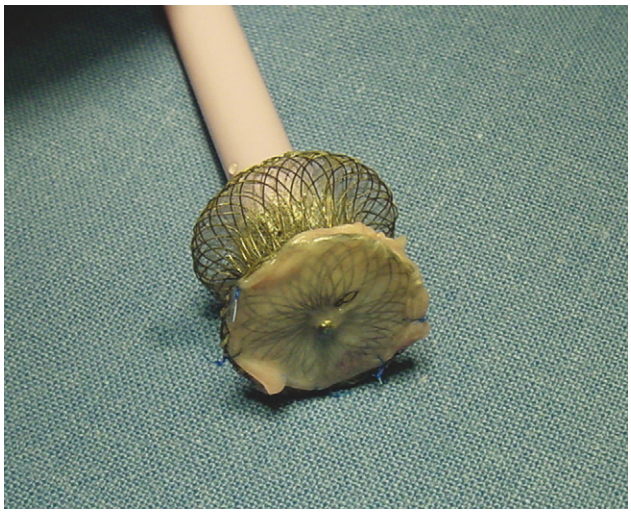

Fig. 2. Front view of 12 mm Amplatz occluder with the pericardial cuff on the ventricular side. The device is mounted into a 30F sheath to simulate the deployment of 25 mm stented valve and its deployment is driven by semi rigid wire.

ventricular pressure and therefore, a technical improvement is needed to ensure the haemostasis. Our hypothesis is that, adding a pericardial cuff on the ventricular side of a standard sutureless device for interatrial septal defects could be an easy and inexpensive method to safely close the ventricle access.

We designed an animal study to compare the consistency of a sutureless repair of the left ventricle access using nitinol occluder with and without pericardial cuff on the ventricular side.

2. Materials and methods

2.1. The occluder

The occluder 12 mm Amplatz (AGA, Golden Valley, MN, USA) is made of nickel–titanium alloy having pre determined thermal memory shape. It consists of two square heads squeezing ventricle wall in between them, sealing the ventricular defect. A third element, a semi rigid guide wire, is secured to the device for driving the deployment. This element is unscrewed once the deployment is completed. The device is mounted into a 30F sheath to simulate the deployment of 25 mm stented valve. The deployment starts into the left ventricle with the release of the endocardial square head. The guide wire is gently pulled back until the square head is in contact with ventricle wall. The second head is then released pulling back the sheath and the guide wire is unscrewed.

To improve its sealing property, a pericardial patch 3 cm $\times$ 3 cm was sutured with 6-O prolene to the ventricular head of the occluder (Fig. 2).

The pericardial cuff does not affect the pushing/pulling force required to displace the occluder inside the sheath.

2.2. Study design

An acute in vivo evaluation was performed in 12 adult pigs, 55 $\pm$ 4.3 kg (range 43–56 kg) weigh, equipped with arterial pressure line in the right carotid artery and ECG. Under general anaesthesia, left thoracoscopy was chosen to open the pericardium. One 12 mm port was inserted into the 7th intercostal space for the camera and two 5 mm ports were inserted into the 11th and 5th spaces, respectively. A pericardial window 4 cm $\times$ 3 cm was then created to clearly see cardiac apex. In six animals, a 3 cm $\times$ 3 cm pericardial patch was harvested and sutured onto the ventricular side of the occluder. After heparin injection (100 U/kg), under ICUS (Sequoia) inserted into the right femoral vein, and fluoroscopic control, we inserted the 30F sheath into the epigastric area through the cardiac apex, up to the left ventricle, simulating the approach for off-pump aortic valve replacement. The sheath was then removed and the ventricle access was closed with the standard occluder in six animals and with the cuffed occluder in the other six animals (Fig. 3, Video 1). Animals were then followed-up for 3 h, collecting haemody-

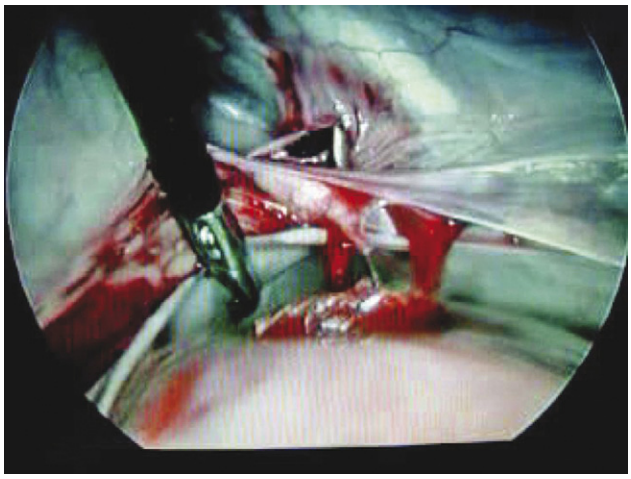

Fig. 3. Videothoracoscopic view of pig's heart. The 30F defect of the free wall of the left ventricle has been repaired using an occluder. The guide wire that holds the occluder is still connected to the nitinol device.

Table 1
Haemodynamic data and blood loss volume during the occluder deployment to close the ventricle access used for transventricular aortic valve replacement

	Baseline		During deployment		After deployment	
	Standard	Cuffed	Standard	Cuffed	Standard	Cuffed
Mean arterial pressure	56 ± 5 mmHg		48 ± 5 mmHg	45 ± 5 mmHg	53 ± 5 mmHg	55 ± 5 mmHg
ECG	Sinus rhythm		Ventricular extrasystole		Sinus rhythm	
Bleeding			80 ± 20 ml	85 ± 20 ml	800 ± 20 ml/3 h	100 ± 5 ml/3 h
					$p < 0.001$	

Two types of occluder were used: standard occluder and occluder cuffed with pericardium.

namics data (heart rate, ECG, blood pressure, pO_2, pCO_2) every 15 min. Pericardial bleeding was assessed using the Smart Suction (Cardio Smart LLC, Fribourg, Switzerland) [7] and the blood lost during the procedure was transfused to the animal. Animals were then sacrificed and gross anatomy examination of the heart carried out.

All the pigs received care in compliance with 'the Principles of Laboratory Animals' formulated by the National Society of Medical Research and 'the Guide for the Care and Use of Laboratory Animals' prepared by the Institute of Laboratory Animal Resources and published by the National Institute of Health (NIH publication 85–23, revised 1985). The protocol was approved by the Institutional Committee on Animal Research.

Data were analysed with SPSS software (Statistical Package for the Social Sciences). Paired *t*-tests were used. Values were reported as mean ± SD.

3. Results

Device was successfully deployed in 12 animals in less than 1 min. ACT was above 200 s in all animals. No major arrhythmias were detected. Monomorphic ventricular extrasistole was the most common arrhythmia. Blood pressure during the deployment was 50 ± 15 mmHg. In the group where the standard occluder was used, bleeding during the deployment was 80 ± 20 ml and after the deployment was 800 ± 20 ml over 3 h. In the group where the cuffed occluder was used, bleeding during the deployment was 85 ± 20 ml and after the deployment was 100 ± 5 ml over 3 h. In the cuffed group, bleeding was significantly lower than the standard group, *p*-value being <0.001.

Gross anatomy examination demonstrated the correct positioning of the device. Detailed results are reported in Table 1.

4. Discussion

The transventricular approach for off-pump aortic valve replacement with stented valves is considered the next revolution in the cardiac surgery and its impact in aortic valve disease treatment will be as important if not more, than that of the angioplasty in coronary diseases.

One of the key steps of the transventricular approach is the closure of the ventricular defect. Every cardiac surgeon who has experimented knows that safely close a 30F hole of the free wall of the left ventricle is a challenging procedure if there is no support of the extracorporeal circulation. Moreover, since all the procedure is done percutaneously, the closure of the left ventricle defect seems almost impossible.

The aim of this study was to assess if it is possible to do something that seems to be impossible simply by applying the smart material technology.

The concept of using a two square heads nitinol device to close cardiac wall defects has been extensively proved [8] and nowadays the endovascular closure of patent foramen ovale is considered a routine procedure. The 12 mm Amplatz occluder has the same geometry as the one used for interatrial septal defect closure, with the distance between the two heads that increases up to 7 mm taking into account the thickness of the ventricle wall. Fig. 3 shows how the occluder looks like on the left ventricle surface.

However, the standard occluder caused 800 cc bleeding over 3 h and is unsuitable for clinical use. But simply adding a pericardial cuff on the ventricular side, we were able to dramatically improve its capability to control the haemostasis as demonstrated by a significant reduction of blood loss. Before clinical application, however, more improvements are necessary. One concern is of the ventricle thickness: in the present configuration, the occluder does not work in case of left ventricle hypertrophy because the epicardial head will stay crimped into the ventricle wall. Finally, we should define a back up strategy in case the device is lost during the deployment as it happens during the endovascular closure of patent foramen ovale.

This study, even with several limitations, has demonstrated that the described nitinol device could be the solution we were looking for to complete the transventricular approach for off-pump aortic valve replacement. The occluder is easy to use and the procedure is feasible and reproducible. We believe that this easy and costless procedure opens the way for endoscopic, off-pump, transventricular aortic valve replacement.

References

[1] Davies H, Lessof MH, Roberts CI, Ross DN. Homograft replacement of the aortic valve: follow-up studies in twelve patients. Lancet 1965;62:926–9.
[2] Lutter G, Kuklinski D, Berg G, Von Samson P, Martin J, Handke M, Uhrmeister P, Beyersdorf F. Percutaneous aortic valve replacement: an experimental study I. Studies on implantation. J Thorac Cardiovasc Surg 2002;123(4):768–76.
[3] Andersen HR, Knudsen LL, Hasenkam JM. Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs. Eur Heart J 1992;13(5):704–8.

[4] Boudjemline Y, Bonhoeffer P. Steps toward percutaneous aortic valve replacement. Circulation 2002;105(6):775—8.
[5] Zhou JQ, Corno AF, Huber CH, Tozzi P, von Segesser LK. Self-expandable valved stent of large size: off-bypass implantation in pulmonary position. Eur J Cardiothorac Surg 2003;24:212—6.
[6] Huber CH, Tozzi P, Corno AF, Marty B, Rucht P, Gersbach P, Nasratulla M, von Segesser LK. Do valved stents compromise coronary flow? Eur J Cardiothorac Surg 2004;25:754—9.
[7] Mueller X, Tevaearai HT, Horisberger J, Ausburger M, Boon Y, von Segesser LK. Smart suction device for less blood trauma: a comparison with Cell Saver. Eur J Cardiothorac Surg 2001;19(4):507—11.
[8] Cao QL, Du ZD, Koenig P, Heitschmidt M, Rhodes J, Hijazi ZM. Intermediate and six month results of the profile of the Amplatzer septal occluder as assessed by transesophageal echocardiography. Am J Cardiol 2001;88(7):754—9.

Appendix A. Conference discussion

Dr P. Kappetein (*Rotterdam, The Netherlands*): What do you think will happen with the occluder at the long term, have you any idea? The pigs were sacrificed quite early, but what do you think will happen in the long term with it?

Dr Tozzi: I showed here just data from an acute study but we did also a chronic study, and after 3 months the occluder is covered by a thin layer of scar tissue, and the tissue around the occluder is also scarred. So if you want, in the worst hypothesis, you can simulate this hole to a very small infarcted area. It is small. Of course, you have to create a hole in the left ventricle. This is a small price to pay.

Dr Kappetein: Have you seen in your long-term studies any bleeding complications in the hours after the operation if your observations are longer than what you described here?

Dr Tozzi: No, we didn't experience that. You mean after the 3 h?

Dr Kappetein: Yes.

Dr Tozzi: No, because if it works, it will last for, we hope, longer years, but if it does not work, you have traumatic bleeding, as I just showed you.

Dr C. Mestres (*Barcelona, Spain*): Just one comment. This is very old business because the transventricular approach has been used for decades and closed mitral commissurotomy and any other type of transventricular approach. So if there is some scar tissue do you believe it may have some potential for dilatation of the apical area, false aneurysms, these kinds of things that have already been seen before?

Dr Tozzi: Could be, of course, but once again, this is a preliminary study and I think we have, on the other side, lots of benefit to doing this procedure in patients. We think we will be able to do this percutaneously. So it will be a great improvement compared to what we have today.

Appendix B. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.ejcts.2006.07.027.